SESSION II

METHODOLOGY ISSUES

PMI1

FROM HEALTH-RELATED QOL TO UTILITY—IS THERE A WAY?

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OBJECTIVE: To predict utility values from health-related quality of life (HRQL) assessments could, if possible, be a fruitful way to use HRQL assessments for health economic evaluations. With this in mind, we compared values for SF-6D, an index derived from the domain values of SF-36 by an algorithm from Brazier et al., with values from the EuroQol instrument, the EQ-5D index, and the EQ-VAS (Visual Analog Scale).
METHODS: Data from two surveys of patients with respiratory disease were used in this comparison. The first data set was from 120 patients in the northern part of Sweden with COPD, and the other dataset from 206 patients in Hungary suffering from asthma. Both surveys covered patients with different severity of the disease. The two datasets were analyzed separately. The EQ-VAS values were rescaled from a range of 0–100 to a 0–1 range.
RESULTS: Results are consistent for the two different data sets and shows an expected gradient for severity groups in both cases. SF-6D has on the average slightly lower values than EQ-5D but higher than EQ-VAS (Mean for COPD: 0.74 vs 0.78 and 0.65; ASTHMA: 0.69 vs. 0.70 and 0.62). On the other hand, both EQ-5D and EQ-VAS have larger variation with a substantial proportion of patients reaching maximum or minimum achievable values. Correlations between the different indices are deceptively high because of extreme values (r for COPD: 0.75–0.69; ASTHMA: 0.70–0.49).
CONCLUSION: SF-6D shows a response pattern more in line with intuitive expectation than EQ-5D and EQ-VAS, which both seem to have a ceiling (and floor) problem.

PMI2

ESTIMATING PREVALENCE AND SURVIVAL BY STAGE OF CANCER FROM THE US SEER DATABASE: COLORECTAL CANCER

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OBJECTIVE: To understand disease burden, prognosis, and survival, and estimate target patient populations for treatment, knowing the prevalence of patients by their clinical stage of disease (AJCC/UICC/TNM) is important. However, such data is not readily available in the published SEER (Surveillance, Epidemiology and End Results) statistics. Moreover, the SEER definitions for staging cancer into local, regional, and distant has changed from 1973–98, and do not coincide with the AJCC clinical stages of I, II, III, and IV. The latter has also undergone five editions from 1978–1997. Colorectal cancer is the third most common incident cancer in the US, with good prognosis and survival if detected early. We estimated the prevalence and survival of colorectal cancer by clinical stage.
METHODS: From the August 2001 release of the SEER database, there were 281,940 cases with a diagnosis of colorectal cancer and complete follow-up through December 31, 1998. The different staging systems of AJCC, TNM, SEER 2000, SEER 1977, SEER Historic Coding, and Dukes/Astler-Collins were summarized and compared, showing the differences and the overlap in the staging systems. Colorectal cancer cases diagnosed from 1988–1998 (n = 129,664) were recoded to the AJCC coding system by SEER. In order to estimate age-adjusted prevalence by stage for the year 2001, we calculated the 1998 age specific prevalence. This latter figure was standardized to the 1990 US standard population to estimate the age-adjusted prevalence, which was then projected onto the 2001 US population estimates to calculate an estimated age-adjusted prevalence in 2001 by stage of disease.
RESULTS: The estimated year 2001 prevalence of colorectal cancer and median survival by AJCC stage were: Stage I, n = 228,958, 9.7 yrs.; Stage II, n = 223,936, 6.7 yrs.; Stage III, n = 145,307, 3.9 yrs.; and Stage IV, n = 28,009, 0.8 yrs.
CONCLUSION: Colorectal cancer in the US was found to have decreasing prevalence and survival with increasing clinical stage (severity).

PMI3

DEVELOPMENT OF DESCRIPTIONS OF TREATMENTS FOR COLORECTAL CANCER FOR USE IN PREFERENCE MEASUREMENT

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OBJECTIVE: When using non-patients as respondents in health state preference measurement, it is necessary to develop accurate descriptions of treatment alternatives and health states patients may be likely to experience. We developed descriptions of commonly used treatment modalities for colorectal cancer (CRC) and ensuing health states for use in subsequent preference measurement studies.
METHODS: Following a literature review and clinical expert input, we identified four commonly used treatment modalities for CRC. Clinical data for each of the modalities were abstracted from the literature, and reviewed by

oncologists to confirm if the literature descriptions of the modalities were consistent with experience in clinical practice. Draft descriptions were then prepared, and critically reviewed by patients from each of the treatment modalities for not only accuracy and relevance but also comprehensibility. Patients were also specifically instructed in these qualitative interviews to describe the impact of their treatment modalities on their everyday lives, to ensure that the ensuing descriptions captured relevant patient outcomes and were phrased in language used by patients. Finally, interviews were carried out with lay persons to review the descriptions for clarity and comprehensibility.
RESULTS: The three commonly used treatment modalities for CRC were Modified de Gramont, Mayo, and Xeloda. It was decided to describe each modality in terms of efficacy, adverse events, administration procedures, and patient outcomes. For ease of comprehension, patients and lay persons suggested presenting the information in separate sections. Subjects were satisfied that the ensuing descriptions accurately captured the relevant issues and were comprehensible.
CONCLUSION: We have successfully prepared accurate and comprehensible descriptions of treatment modalities and ensuing health states in CRC. These descriptions may be useful in health state preference measurement studies using non-patients as respondents.

PMI4

ASSESSING RESOURCE USE WITHIN ONCOLOGY INDICATIONS: A METHODOLOGICAL APPROACH TO CONDUCTING RETROSPECTIVE DATA ANALYSES

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Reimbursement and other health policy decisions may be highly influenced by analysis of claim-based utilization. Secondary analyses of medical claims data to describe patterns of resource utilization often rely on arbitrarily defined timeframes. In oncology, where treatment is in short defined time periods, both simple use-per-time averaging and illness-episode approaches based on primary diagnosis and treatment may inaccurately estimate resource utilization.
OBJECTIVE: This study examined the variation in utilization of an injectable oncology supportive care agent using three different analytical techniques.
METHODS: Patients with a principal diagnosis of cancer and use of filgrastim were extracted from the 1996–98 Medicare 5% claims database. Patterns of resource utilization were compared with 1) simple use-per-time averaging; 2) illness-episode aggregation; and 3) per-chemotherapy cycle aggregation. Descriptive statistics for the number of days of utilization are reported.
RESULTS: A total of 5,160 patients yielding 2.9 million claims were analyzed. The range of filgrastim resource utilization varied considerably depending on the analysis technique used: simple use-per-time was 1 to 159 days; illness-episode aggregation was 1 to 51 days; and per-chemotherapy cycle aggregation was 1 to 15 days. For all analyses, the medical claims data do not provide adequate rationale for use or days of utilization, and therefore this database has limited value as a guide to future decision-making. In addition, the analysis was limited in the ability to accurately identify chemotherapy regimens; differentiate prophylactic vs. treatment use of supportive agents; and in describing oral chemotherapy use, dose delays and reductions, and reasons for chemotherapy alterations.
CONCLUSION: Resource utilization in oncology is highly influenced by the data source and the analysis method chosen, which may not allow for an accurate understanding of practice patterns. Only by understanding these limitations in specific disease areas can the medical decision-making be improved leading to better patient outcomes.

PMI5

FACTORS FOR THE VARIATION IN THE PREVALENCE OF ARTERIAL PERIPHRIAL DISEASE—STUDY IMPLICATIONS FOR OUTCOMES RESEARCH

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Prevalence of peripheral arterial disease (PAD) has been constantly grown over the past decades. However, inconsistent data on PAD prevalence from published literature were limited in use for either research or disease management.
OBJECTIVES: The purposes of this review were to summarize published PAD prevalence and to identify factors that may cause the variation in PAD prevalence.
METHODS: English-language studies published between 1980 to December 2001 were identified through a MEDLINE search.
RESULTS: Thirty-one studies on PAD prevalence were identified. The present review showed that the prevalence of PAD varied and it was highly dependent on the definition of clinical presentations. Additional factors for the variation included type, sensitivity and/or specificity of diagnostic tests for screening and the distribution of risks for PAD including age, male gender, smoking, diabetes and dyslipidemia. The review showed that the prevalence of PAD varied ranging from 1.2% in general population to 29% in high-risk patients. After adjusting for age, gender and clinical presentation, the overall PAD prevalence and the prevalence with intermittent claudication were 8.7% to 26.5% and 1.6% to 2.9% respectively. Prevalence of PAD was often higher (2 to 7 times) in studies using a combination of noninvasive tests, patient reported history and physical examinations for diagnosis than that in those studies using only patient history plus